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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,767	03/11/2000	Eugene de Juan JR.	49.603 (1699)	5862

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EXAMINER

BAXTER, JESSICA R

ART UNIT PAPER NUMBER

3731

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/523,767

Applicant(s)

DE JUAN ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 23-54, 56-62 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-21, 55 and 63-65 is/are rejected.
- 7) ☐ Claim(s) 14 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/23/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 42-54 and 56-62 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: a separate insertion tool for inserting the entry alignment device into the eye is claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 42-54 and 56-62 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Newly submitted claim 66 is dependent on claim 26, a non-elected claim, thus claim 66 is withdrawn from consideration.

Drawings

3. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on December 23, 2002 have been accepted. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

4. The objection to Figures 7A and 7B is withdrawn.

Claim Rejections - 35 USC § 112

5. Claim 6 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is withdrawn.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1- 12, 55 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,547,473 to Peyman in view of U.S. Patent No. 5,817,099 to Skolik et al

Skolik discloses a method comprising the steps of providing an entry alignment device and inserting the entry alignment device into the eye so as to form entry apertures (Column 4 lines 15-20). Skolik does not disclose that the entry apertures are in the conjunctiva and sclera, but does disclose that the device can be used in different procedures in the eye (Column 3 lines 61-67). Peyman teaches that a device may be inserted into the eye through the conjunctiva and the sclera (FIG. 5) to perform a retinal procedure on the eye (Column 4 lines 47-52). Skolik discloses that an entry alignment device should be used in ocular surgery to protect the surrounding tissue from mechanical and thermal injury (see abstract lines 5-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an entry alignment device in the

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method of Peyman in order to protect the surrounding tissue from mechanical and thermal injury and, in addition, Skolik teaches that the device may be used in procedures in other parts of the eye.

Regarding claims 2, 3 and 10, Skolik discloses the claimed invention except for the size necessary to ensure a self-sealing entry aperture. Peyman teaches that the devices used in his procedure are small enough to allow the wound to be self-sealing (Column 4 line 65-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to size the entry alignment device of Skolik small enough to be self-sealing in order to avoid the use of sutures.

Regarding claims 4, 5, 8 and 9, Peyman discloses that a surgical instrument used in the procedure is less than 25 gauge and may be an infusion cannula or an vitreous cutter or aspirator (Column 2 lines 6-18 and Column 4 lines 38-46).

Regarding claim 6, Skolik discloses that the entry alignment device is in the form of a metal cannula (see Column 5 lines 47-51).

Regarding claims 7 and 55, Skolik discloses that a plurality of entry alignment devices may be inserted into the eye (see Column 12 lines 43-45).

Regarding claims 11 and 12, Peyman discloses that the device is inserted at an angle with respect to a normal to the eye (FIG. 5). The normal to the eye can be any line that is perpendicular to the eye.

Regarding claim 63, Peyman discloses that the infusion cannula may be inserted directly through the sclera and conjunctiva or through the entry alignment device (Column 4 lines 27-46).

8. Claims 13, 15-21, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,487,725 to Peyman in view of Skolik et al. '099, further in view of U.S. Patent No. 5,919,158 to Saperstein et al.

Peyman discloses the claimed invention except for the insertion of a light source.

Saperstein teaches the use of a light source to illuminate an area the surgeon is working on (see Column 5 lines 13-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to insert a light source in order to illuminate the area in which the surgeon is working.

Regarding claim 13, Peyman discloses inserting a high-speed vitreous cutting/aspirating instrument and removing vitreous gel using the high-speed vitreous cutting instrument and implementing a corrective procedure for the retina (see Column 4 line 63 – Column 5 line 18).

Regarding claims 15, 16 and 19, Skolik discloses the claimed invention except for the size necessary to ensure a self-sealing entry aperture. Peyman teaches that the devices used in his procedure are small enough to allow the wound to be self-sealing (Column 4 line 65-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to size the entry alignment device of Skolik small enough to be self-sealing in order to avoid the use of sutures.

Regarding claim 17, Skolik discloses that the entry alignment device is in the form of a metal cannula (see Column 5 lines 47-51).

Regarding claim 18, Peyman discloses that a surgical instrument used in the procedure is less than 25 gauge and may be an infusion cannula (Column 4 lines 38-46).

Regarding claims 20 and 21, Peyman discloses that the step of inserting includes inserting the instruments, hence the entry alignment device, at an angle less than 45 degrees with respect to a normal to the eye.

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Regarding claims 64 and 65, Peyman discloses that the infusion cannula may be inserted directly through the sclera and conjunctiva or through the entry alignment device (Column 4 lines 27-46).

Allowable Subject Matter

9. Claims 14 and 22 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

10. Applicant's arguments filed December 23, 2002 have been fully considered but they are not persuasive.

11. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the device is inserted without an incision being made in the eye) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


JRB

March 5, 2003


MICHAEL J. MILANO
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TECHNOLOGY CENTER 3700